From: <u>Jay Field</u>

To: <u>Eric Blischke/R10/USEPA/US@EPA</u>

Subject: Re: Bioassay Interpretation at Portland Harbor

Date: 06/15/2009 12:53 PM

```
Eric, that is my understanding also.
Jay
Blischke.Eric@epamail.epa.gov wrote:
> I think it is prior to establishment of the reference envelope.
                                          Jay Field
                                           <Jay.Field@noaa.
                                          aon>
                                                                                                                                                                                                     Тο
                                                                                                                Robert Gensemer
                                          06/15/2009 11:23
                                                                                                                <rgensemer@parametrix.com>
                                                                                                                                                                                                     CC
                                                                                                               Eric Blischke/R10/USEPA/US@EPA,
Benjamin Shorr
                                                                                                               Benjamin Shorr@noaa.gov>, Burt Shephard/R10/USEPA/US@EPA, Chip Humphrey/R10/USEPA/US@EPA, Joe Goulet/R10/USEPA/US@EPA, Robert Neely <Robert.Neely@noaa.gov>
                                                                                                                                                                                       Subject
                                                                                                               Re: Bioassay Interpretation at Portland Harbor
> I do not see anything in MacDonald and Landrum about how to deal with 
> statistical significance once the reference envelope is established. If 
> we're talking about samples that would be classified as Level 1, I could 
> see some rationale for considering them as Level 1-. for samples that 
> are Level 2 or greater (>20% difference from 95th percentile of the 
> reference envelope), those are likely low-power results and should 
> retain their classification. FYI, according to my calculations, there 
> are 24, 7, and 1 non-significant samples for Levels 1,2,&3 respectively.
     Jay
     Robert Gensemer wrote:
    Eric: That is my understanding as well. The 2008 MacDonald and Landrum report is pretty clear about this too, and further points out the need for the test of statistical significance (and the RE approach in general) to be conducted separately and independently for each of the four bioassay endpoints.

-Bob
                       - Bob
                      ----Original Message----
From: Blischke.Eric@epamail.epa.gov [
mailto:Blischke.Eric@epamail.epa.gov]
Sent: Monday, June 15, 2009 9:35 AM
To: Jay Field
Cc: Benjamin Shorr; Shephard.Burt@epamail.epa.gov;
Humphrey.Chip@epamail.epa.gov; Goulet.Joe@epamail.epa.gov; Robert
Gensemer; Robert Neely
Subject: Re: Bioassay Interpretation at Portland Harbor
                      I agree that statistical significance was not part of the reference envelope approach but I thought that statistical significance needed to be taken into account in the comparison to
                       negative control.
                       Eric
                                                          Jay Field
                                                           <Jay.Field@noaa.
                                                           qov>
                       То
                                                                                                                               Eric
                       Blischke/R10/USEPA/US@EPA
                                                           06/12/2009 04:15
                                                                                                                                Burt
                       Shephard/R10/USEPA/US@EPA,
                                                                                                                                Chip
                      Humphrey/R10/USEPA/US@EPA,
                                                                                                                               Joe Goulet/R10/USEPA/US@EPA,
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rgensemer@parametrix.com, Robert Neelv <Robert.Neely@noaa.gov>, Benjamin Shorr <Benjamin.Shorr@noaa.gov> Subject Re: Bioassay Interpretation at Portland Harbor Eric, Attached is a spreadsheet that shows the data we have for the 293 tox samples and the calculated effect levels, which were based on the values $\frac{1}{2}$ for the 4 endpoints in table RE-2. As previously mentioned, we did not take into account statistical significance, since it was our understanding that statistical comparisons are not part of the reference envelope approach as described by MacDonald & Landrum. Have we received any of the information that you requested from ${\tt John}$ Toll and ${\tt LWG?}$ Have a good weekend, Jay Blischke.Eric@epamail.epa.gov wrote: All, I had another voicemail exchange with John, he would like to have this discussion next Tuesday, June 16th. Does that work? I will continue to work on getting some information ahead of time. Eric Burt Shephard/R10/USE PA/US То Eric Blischke/R10/USEPA/US@EPA 06/08/2009 11:44 CC Chip Humphrey/R10/USEPA/US@EPA, jay.field@noaa.gov, Joe Goulet/R10/USEPA/US@EPA, rgensemer@parametrix.com

Subject

Re: Bioassay Interpretation at Portland Harbor (Document link: Eric Blischke) Eric, I think Jay's suggestion is a good one, we need to know exactly what LWG has done before we can identify the discrepancies. For now, we don't know what they've done that differs from us. I also think we should bring Don MacDonald into the discussions with LWG. Surprisingly given my schedule since January, I'm actually in the office all week this week, although most of Wednesday is tied up with Upper Columbia River site meetings. Best regards, Burt Shephard Risk Evaluation Unit Office of Environmental Assessment (OEA-095) U.S. Environmental Protection Agency, Region 10 1200 6th Avenue Seattle, WA 98101 Telephone: (206) 553-6359 Fax: (206) 553-0119 e-mail: Shephard.Burt@epa.gov "If your experiment needs statistics to analyze the results, then you ought to have done a better experiment" - Ernest Rutherford Eric Blischke/R10/USE PA/US То Burt Shephard/R10/USEPA/US@EPA, 06/08/2009 10:35 rgensemer@parametrix.com, Joe

> > > >

AM Goulet/R10/USEPA/US@EPA, CC

Humphrey/R10/USEPA/US@EPA

Chip

Subject

Interpretation at

Bioassay

Portland Harbor

At the AOPC meeting, it became apparent that our interpretation of the sediment bioassay results did not match the LWG's interpretation. I

am

interested in understanding the basis for this discrepancy. Based on $% \left\{ 1\right\} =\left\{ 1\right$

my

review of the data, the bioassay results match up with the bins that $% \left(1\right) =\left(1\right) \left(1\right) +\left(1\right) \left(1\right) \left(1\right) +\left(1\right) \left(1\right) \left($

we

established in Table RE-2 in our March 31, 2009 direction to LWG (see previous email). Last week, I put in a call to John Toll to try to understand the LWG's interpretation. Although I did not speak

directly

1) The raw response rates differ slightly - e.g., 15% vs. 17%. John does not know why this is the case. 2) Significance Testing. The LWG used the biostats software. He indicated that this is a complicated procedure but that the LWG

followed

the decision tree associated with the software package and did not

make

any choices that were inconsistent with the decision tree. 3) The calculation of the level of the hit (e.g., low, moderate or severe toxicity) based on a comparison to the reference envelope was based on an added 10% to the reference envelop opposed to multiplying

by

the reference envelope value by 1.1 or 1.2.

I would like to set up a time to discuss this sometime this week. Please let me know when you might be available. I will work with John to hopefully have some information that we can use to focus the discussion.

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Thanks, Eric,

Thanks, Eric,

Thanks, Eric,

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(See attached file: PH_ToxRef_090612.xls)

(See attached file: PH_ToxRef_090612.xls)

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